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| 10/813,574 | 03/31/2004 | Sadanandan Bindu | 82484 | 4330 |

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| EXAMINER | |
|---|---|
| AFREMOVA, VERA | |
| **ART UNIT** | **PAPER NUMBER** |
| 1657 | |
| **MAIL DATE** | **DELIVERY MODE** |
| 12/20/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/813,574 | BINDU ET AL. | |
| | Examiner | Art Unit | |
| | Vera Afremova | 1657 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *01 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *1-3 and 11-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/01/2007 has been entered.

Claims 4-10 as amended (10/01/2007) are under examination in the instant office action.

Claims 1-3 and 11-21 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/27/2006.

### *Specification*

The disclosure is objected to because of the following informalities:

Specification contains some empty spaces as intended for disclosure of IDA (International Depository Authority in accordance to the Budapest Treaty) accession numbers of the applicants' mutants characterized by high level of phytase activity.

Appropriate correction is required. In order to avoid a possible "new matter" situation, it is also noted that the instant application appears to be intended for 2 mutants (specification page 1, par. 1) that are EMY 505 and UVY 505 (page 10, par. 2) obtained by mutagenesis from a natural wild type isolate CFR505 that was deposited or re-deposited by applicants as MTCC

5155 but that was used in the prior practice of making batter in home, hotel and catering centre facilities (specification page 7, example 1).

***Claim Rejections - 35 USC § 112***

***Deposit***

Claims 4-10 remain/are rejected under 35 U.S.C. 112, *first paragraph,* as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At least some of the claims require one of ordinary skill in the art to have access to "yeast mutants" derived from a parent strain MTCC 5155 (CFR 505) belonging to the species of *Candida versatilis*. Because these "mutants" are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the "mutants" are not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by deposit of these microorganisms. The specification does not disclose a repeatable process to obtain the microorganisms and it is not clear from the specification or record that the microorganisms are readily available to the public.

For example: the disclosed mutants EMY 505 and UVY 505 that are characterized by the claimed phytase activity ranging between 140 U/g and 197 U/g are obtained by mutagenization of the claimed strain MTCC 5155 (same as CFR 505) and the method of making the mutants EMY 505 and UV 505 by mutagenization is clearly unpredictable (example 2, specification

pages 8-10). The claimed parent strain MTCC 5155 (same as CFR 505) fails to reduce phytic acid level in dough as disclosed (specification page 11, last par.).

The instant rejection may be overcome by establishing that each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein. See 37 CFR 1.801-1.809.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or a statement by an attorney of record over his/her signature and registration number, stating that the deposit has been made under the Budapest Treaty and that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent would satisfy the deposit requirement. See 37 CFR 1.808.

***Indefinite***

Claims 4-10 as amended remain/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is rendered indefinite, uncertain, confusing and improper by the phrase "strain comprising yeast mutants" as presently recited in the step (c ) in the method of making dough. The microbial strain is a specific entity by itself and the mutants derived from one parent strain will be some other strains distinct from the patent strain. The terminology used in the claim is inconsistent with the art accepted meaning.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999).

In the light of the as-filed specification it appears that the presently claimed phrase "obtaining a mutated, permeabilized strain of a yeast *Candida versatilis* MTCC 5155, said strain comprising yeast mutants having phytase activity ranging between 140 U/g and 197 U/g" is intended to mean "obtaining a mixture of permeabilized yeast cells having phytase activity ranging between 140 U/g and 197 U/g wherein the yeast cells belong to *Candida versatilis* strain EMY 505 or to *Candida versatilis* strain UVY 505". See specification page 10, par. 2. The parent strain MTCC 5155 as disclosed does have phytase activity ranging between 140 U/g and 197 U/g as claimed. The parent strain is distinct from its mutants by morphology as disclosed by applicants (page 10. lines 1-2) and by phytase activity (page 11, par. 2 and page 10. par. 2).

***New matter***

Claims 4-10 as amended remain/are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Insertion of the limitation drawn to the use of an yeast strain "MTCC 5155" "having phytase activity ranging between 140 U/g and 197 U/g" that has no support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus that would show possession of the concept of the use of the specific yeast strain "MTCC 5155" with "phytase activity ranging between 140 U/g and 197 U/g" in order to obtain dough with 10-40% reduction in the level of phytic acid.

The claimed strain "MTCC 5155" is the same as strain "CFR 505" that is found in the batter used in the home-made, hotel and catering centre practices (see specification page 7, example 1 and the deposit papers filed with the response 10/01/2007). The strain CFR 50 has phytase activity as high as 90 U/g as disclosed (page 11. par. 2) which is below the presently claimed range between 140 U/g and 197 U/g. The strain CFR 505 fails to reduce phytic acid content as disclosed in the as-filed specification (page 11, last par.) to the contrary of the final result or effects in obtaining dough with "10-40% reduction in the level of phytic acid" as encompassed by the instant claims.

There are some exemplified yeast strains that are identified by internal designation numbers EMY 505 and CFR 505 (specification page 6) that have properties and/or effects as encompassed by the instant claims. But these strains are not claimed.

Thus, the newly inserted limitation drawn to the use of the strain MTCC 5155 with "phytase activity ranging between 140 U/g and 197 U/g" in order to obtain "dough with 10-40% reduction in the level of phytic acid" is lacking sufficient support. Therefore, this insertion is considered to be the insertion of new matter in the instant office action for the reasons above.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-10 as amended remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,794,014 (Siren), Quan et al. ("Production of phytase in a low phosphate medium by a novel yeast *Candida krusei*". Journal of Bioscience and Bioengineering. 2001. Vol. 92, No. 2, pages 154-160) and Bindu et al. ("A comparative study on permeabilization treatments for in situ determination of phytase of *Rhodotorula gracilis*". Letters in Applied Microbiology. 1998. 27:336-340).

Claims are directed to a method for reducing phytic acid level in food preparation "Chapathi dough" with an yeast strain belonging to the species of *Candida versatilis* wherein the method comprises step of making "Chapathi dough" by mixing wheat flour, water, salt and the yeast strain(s) and storing the "Chapathi dough" at temperature 10-26°C for 0.5-24 hours, thereby obtaining reduction in the level of phytic acid. Some claims are/are further drawn to the use of the yeast strain(s) cells in a permeabilized form obtained by repeated cycles of freeze-thawing.

The cited patent US 4,794,014 (Siren) discloses a method for reducing phytic acid level in food preparations made from phytate-containing materials (IP6 materials) by using yeast cells as a source of phytase (entire document including col. 3, lines 50-65 and col. 5, lines 22-24). The starting IP6 materials include wheat, wheat bran and wheat flour. In particular example the

method for reducing phytic acid level comprises step of making dough by mixing wheat flour, water, salt and the yeast strain(s) and storing the dough, thereby, obtaining reduction in the level of phytic acid (examples 4 and 8). The cited patent teaches that phytate hydrolysis occurs at temperature ranges 20-70°C, thus, including the presently claimed temperatures. The yeast culture that is used as a source of phytase is generic and/or belongs to baker's yeast or *Saccharomyces*. Thus, the cited patent is lacking particular disclosure about the use of yeast cells belonging to *Candida*.

However, the reference by Quan et al. demonstrates that yeast cells belonging to *Candida* produce high level of phytase (abstracts) and they are capable of biodegrading phytate in food materials including wheat. In particular example wheat phytate is biodegraded or phytate amounts are considerably reduced within 12 hours (fig. 7 and page 159, col. 1, par. 1).

The cited documents US 4,794,014 (Siren) and Quan et al. demonstrate that yeast cells are source of phytase but they are silent about preliminary treatments of yeast cells that are used as source of phytase in the methods for reducing phytic level in food preparation including wheat and/or wheat-containing dough.

However, the reference by Bindu et al. teaches that yeast cells have tough cell walls, that permeabilization treatments provide for a larger amount of released enzymes and that repeated cycles of freeze-thawing are most efficient for enhancing phytase activity in yeast cell preparations (entire document including abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify method for reducing phytic acid level taught by US 4,794,014 (Siren) by using yeast cells belonging to *Candida* with a reasonable expectation of

success in reducing phytic acid level in wheat containing food including dough or "Chapathi dough" because it is well known that yeast cells are used for enzymatic reduction of phytic acid levels in various food and that yeast cells belonging to *Candida* are source of phytase having high enzymatic activity. One of skill in the art would have been motivated to enhance enzymatic activity of yeast cell preparations by permeabilizing yeast cells through repeated freeze-thaw cycles for the expected benefits in increasing levels of phytate biodegradation.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

***Response to Arguments***

Applicant's arguments filed 10/01/2007 have been fully considered but they are not persuasive.

Applicants' arguments do not have any persuasive grounds because they are based on the specific properties of the particular "mutant(s)" or particular strain(s) that is/are not presently claimed such as strain EMY 505 or strain UVY 505. The presently claimed strain MTCC 5155 (same as CFR 505) is not characterized by properties that are relied upon in the arguments. The claimed parent strain MTCC 5155 (same as CFR 505) fails to reduce phytic acid level in dough as disclosed (specification page 11, last par.) in the contrary to the present arguments (page 16, for example). Thus, the cited prior art that teaches the use of generic yeast strains including

yeasts belonging to *Candida* in the method for making dough and reducing phytic contents is considered to be obvious variant of the presently claimed method.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1657

December 17, 2007

VERA AFREMOVA

PRIMARY EXAMINER